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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/804,745

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M19-106

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EXAMINER

FISHER, ABIGAIL L

ART UNIT

PAPER NUMBER

1616

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/804,745	Applicant(s) COHN ET AL.	
	Examiner ABIGAIL FISHER	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6,7 and 89-93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,7 and 89-93 is/are rejected.
- 7) ☒ Claim(s) 93 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/16/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner for your application in the USPTO has changed. Examiner Abigail Fisher can be reached at 571-270-3502.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 16 2008 has been entered. Claims 4-5 and 8-88 were/stand cancelled. Claims 1-3, 6-7 and 89-93 are pending.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on April 16 2008 was considered by the examiner.

Claim Interpretation

Claim 1 and the claims that depend from claim 1 contain the transitional language “consisting essentially of”. For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.” If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of “consisting essentially of,” applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *PPG Industries Inc. V Guardian Industries Corp.* 48 USPQ2d 1351 (Fed. Cir. 1998) and *In re De Lajarte* 337 F.2d 870, 143 USPQ 256 (CCPA 1964) **See MPEP 2111.03.**

The instant specification does not define the term “consisting essentially of” in a manner that would allow one skilled in the art to determine what basic and novel characteristics are being materially affected.

Claim Objections

Claim 93 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 93 claims A is a polyester unit derived from the polymerization of lactide monomers. Claim 93 depends

Art Unit: 1616

from 92 which claims the exact same limitation. Therefore, claim 93 is not further limiting.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 6-7 and 89-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spenlehauer et al. (US Patent No. 5683723, cited in the Office action mailed on 8/14/07) in view of Domb et al. (5578325).

Applicant Claims

Applicant claims a polymeric composition consisting essentially of cross-linked AB diblocks where A is a polyester unit and B is a polyoxyalkylene polymer which is end-capped with a non-reactive group.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Spenlehauer et al. is directed to nanoparticles based on polyoxyethylene and polylactic acid block copolymer. The polymer synthesized by Spenlehauer et al. are block polymers comprising PLA (polylactic acid) and PEG (polyethylene glycol). Formula (I) is the copolymer of the invention. It is taught that one end, the alkylene oxide end, is terminated (R') with a hydrogen or alkyl group containing 1 to 4 carbon atoms with methyl being preferable (column 2, lines 12-25). It is taught that nanoparticles are used for injection into a living organism for human or animal pharmacy or for medical diagnosis (column 4, lines 14-19).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Spenlehauer et al. do not teach that the polymers can be cross-linked. However, this deficiency is cured by Domb et al.

Domb et al. is directed to nanoparticles of non-linear hydrophilic-hydrophobic multiblock copolymers. The polymers include polylactic acid and polyethylene glycol

(figure 2g). It is taught that substances can be incorporated with the multiblock copolymers for diagnostic purposes. For example, gamma-labeled injectable nanoparticles can be utilized to monitor biodistribution of the injectable particle in vivo. Gamma-emitting magnetic moieties can be covalently attached to the polymeric material. Alternatively the copolymer can be covalently bound to a biologically active molecule such as Fab or Fab₂ antibody fragments for diagnostic purposes (column 12, lines 23-59).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to combine the teachings of Spenlehauer et al. and Domb et al. and cross-link the polymers with gamma-emitting moieties or biologically active molecules. One of ordinary skill in the art would have been motivated to cross-link the polymers of Spenlehauer et al. with gamma-emitting moieties or biologically active molecules as Spenlehauer et al. teach that the polymers can be utilized for diagnostic purposes and Domb et al. teach that incorporation of gamma-emitting moieties or biologically active molecules with multiblock polymers like those of Spenlehauer et al. leads to nanoparticles that can be utilized for diagnostic purposes.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/
Primary Examiner, Art Unit 1616